Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the Effectiveness of Zingiber zerumbet ointment with Diclofenac Gel on clinical symptoms in patients with Knee osteoarthritis: A randomized, double-blind, controlled trial

Protocol summary

Study aim

Determine the effect of Zingiber Zerumbet (ZZ) ointment on the treatment of knee osteoarthritis

Design

In this research, 80 eligible patients referring to Rheumatology Clinic of Mostafa Khomeini Hospital were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups, By block randomization method; For the drug group, ZZ ointment and acetaminophen is prescribed and for the positive control group diclofenac and acetaminophen.

Settings and conduct

80 patients with osteoarthritis accepted by the rheumatologist based on ACR classification criteria, After receiving written consent, they are randomly assigned to two groups of drugs and positive control. Drugs will be encoding, same shape and without the name, 1 grams, four times a day for 4 weeks will prescribe to intervention groups(Both groups). Patients are allowed to take acetaminophen if they have pain; Patients two weeks after the start and after 4 weeks of treatment (end of study) are examined by the rheumatologist and the relevant data through interviews and examination of them will be collected; And the WOMAC questionnaire is completed; Also, blood tests including CBC, BUN, Cr, AST, ALT, ALP, CRP , IL1 and IL6 are taken at the beginning of the test, and the tests are repeated at the end of the 4th week.

Participants/Inclusion and exclusion criteria

Inclusin criteria: Outpatient patients with knee osteoarthritis based on clinical criteria of ACR Exclusion criteria: Patients with Secondary osteoarthritis; Pregnancy; Joint Replacement; Knee corticosteroid injection in the past 3 months; Patients with active Renal and Liver Diseases.

Intervention groups

In the intervention group, the ZZ ointment administered topically in the knee area 3 times a day for 4 weeks. In the positive control group, diclofenac gel was given topically in the knee area 3 times daily for 4 weeks.

Main outcome variables

Knee pain according to WOMAC questionnaire; The stiffness of the joint according to the WOMAC questionnaire; Limitations of physical activity based on WOMAC questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170428033670N1**
Registration date: **2018-01-21, 1396/11/01**
Registration timing: **prospective**

Last update: **2018-01-21, 1396/11/01**
Update count: **0**

Registration date

2018-01-21, 1396/11/01

Registrant information

Name
hasan kiani
Name of organization / entity
shahed university
Country
Iran (Islamic Republic of)
Phone
+98 21 5121 4055
Email address
hasan-kiani@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Immunology Research Center, University of shahed

Expected recruitment start date
2018-01-31, 1396/11/11
Expected recruitment end date
2018-06-19, 1397/03/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Zingiber zerumbet ointment with Diclofenac Gel on clinical symptoms in patients with Knee osteoarthritis: A randomized, double-blind, controlled trial

Public title
Effect of Zingiber zerumbet pomade in treatment of knee arthrosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Out-patients who suffer osteoarthritis based on clinical criteria of ACR
Exclusion criteria:
Those who need more than 2 grams of acetaminophen daily Those who need to use other oral or intravenous analgesic Sensitivity to study drugs Patients with Secondary osteoarthritis caused by rheumatic diseases such as rheumatoid arthritis Pregnancy Joint Replacement Concomitant use of glucosamine and chondrotin sulfate Knee corticosteroid injection in the past 3 months Oral or topical use of Corticosteroid in 14 past days Other Articular corticosteroid injection in the past 1 months Mussle corticosteroid injection in the past 1months Skin Diseases in Knee Radiculopathy and Neuropathy Alcohol addicted, Drug Abuse Patients with active Renal, Liver, and Peptic Ulcer Diseases Age under 30 or over 80 years
Age
From **30 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The allocation of patients to Drug and Positive Control Groups, will be done by block randomization method. Zingiber Zerumbet (ZZ) Ointment and diclofenac gel are packed in completely similar containers and in weight; Each container is identified by a code. The code and contents of containers will be recorded by a third party in a sheet. The drugs are available to the researcher in the binary blocks of ZZ and diclofenac and ultimately distributed among the patients, the investigator and the patient are not aware of the contents of the packages.
Blinding (investigator's opinion)
Double blinded
Blinding description
The drug containers are encoded with the same shape and weight, and are given to the researcher in binary blocks, and then given to the patient; the patient, the investigator, and the analyst in the study are blinded; The medications, are indicated for the data analyst as drug A and drug B
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahed University
Street address
Shahed university, Persian gulf freeway, Tehran,iran
City
Tehran
Province
Tehran
Postal code
3319118651
Approval date
2017-04-05, 1396/01/16
Ethics committee reference number
IR.Shahed.REC.1395.233

Health conditions studied

1

Description of health condition studied
Osteoarthritis
ICD-10 code
M19.9
ICD-10 code description
Arthrosis, unspecified

Primary outcomes

1

Description
pain
Timepoint
Before the intervention, the end of the second week and the end of the fourth week after the start of the intervention
Method of measurement
The Western Ontario and McMaster Universities Osteoarthritis (WOMAC) questionnaire

2

Description
Physical Function
Timepoint
Before the intervention, the end of the second week and the end of the fourth week after the start of the intervention
Method of measurement
The Western Ontario and McMaster Universities Osteoarthritis (WOMAC) questionnaire

3

Description
Stiffness
Timepoint
Before the intervention, the end of the second week and the end of the fourth week after the start of the intervention
Method of measurement
The Western Ontario and McMaster Universities Osteoarthritis (WOMAC) questionnaire

Secondary outcomes

1

Description
Interleukin 1
Timepoint
Before the intervention and the end of the fourth week after the start of the intervention
Method of measurement
Venous blood sample

2

Description
Interleukin 6
Timepoint
Before the intervention and the end of the fourth week after the start of the intervention
Method of measurement
Venous blood sample

Intervention groups

1

Description
zingiber zerumbet pomade, Knee local use. Dosage 1 grams per use 4 times a day.
Category
Treatment - Drugs

2

Description
Plus control group: diclofenac gel group. Knee local use. Dosage 1 grams per use4 times a day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mostafa Khomeini Hospital
Full name of responsible person
Hasan Kiani Ahmadabadi
Street address
Mostafa Khomeini Hospital, Italy St, Palestine Street, Tehran
City
Tehran
Province
Tehran
Postal code
1416643491
Phone
+98 21 8896 6131
Email
hasan-kiani@shahed.ac.ir
Web page address
http://www.mkht.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Immunology Research Center of Shahed University
Full name of responsible person
dr tuba ghazanfari
Street address
No. 1471, Immunology Research Center, North Kargar Avenue, Enghlab square, Tehran
City
Tehran
Province
Tehran
Postal code
3319118651
Phone
+98 21 6641 8216
Email
hasan-kiani@shahed.ac.ir
Web page address
http://www.shahed.ac.ir/

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Immunology Research Center of Shahed University
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahed University
Full name of responsible person
hasan kiani Ahmadabadi
Position
MD and PhD student of Iranian Traditional Medicine
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Department of Iranian Traditional Medicine, Shahed University, Persian Gulf Highway, Tehran
City
Tehran
Province
Tehran
Postal code
3319118651
Phone
+98 21 5121 4055
Fax
Email
hasan-kiani@shahed.ac.ir
Web page address
http://www.shahed.ac.ir/

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahed university
Full name of responsible person
Hasan Kiani Ahmadabadi
Position
MD and PhD student of Iranian Traditional Medicine
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Department of Iranian Traditional Medicine, Shahed University, Persian Gulf Highway, Tehran
City
Tehran
Province
Tehran
Postal code
3319118651
Phone
+98 21 5121 4055
Fax
Email
hasan-kiani@shahed.ac.ir
Web page address
http://www.shahed.ac.ir/

Person responsible for updating data

Contact
Name of organization / entity
Shahed university
Full name of responsible person
Hasan Kiani Ahmadabadi
Position
MD and PhD student of Iranian Traditional Medicine
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Department of Iranian Traditional Medicine, Shahed University, Persian Gulf Highway, Tehran
City
Tehran
Province
Tehran
Postal code
3319118651
Phone
+98 21 5121 4055
Fax
Email
hasan-kiani@shahed.ac.ir
Web page address
http://www.shahed.ac.ir/

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available